2.0 Conducting the Tier 1 Screening Risk Assessment

2.1 Introduction

2.1.1 Purpose and Objectives of the Tier 1 SRA

The Tier 1 SRA is a screening-level assessment that employs existing site data and conservative assumptions to support risk management decisions. The principal objectives of the Tier 1 SRA are to provide a scientific basis for deciding whether a site may be eliminated from concern, to identify risk situations that may require immediate attention (in the form of an interim response action), and to determine whether additional ERA (in the form of a BERA) is warranted. The SRA will also aid in focusing the BERA if one is needed. These objectives are consistent with the goals, objectives, and requirements identified in the NCP for the PA/SI (see Section 2.2.1 of the *Regulatory Basis* portion of this website).

2.1.2 Tier 1 SRA Decision Criteria

The risk estimates derived in the Tier 1 SRA will be used to support one of three risk management decisions:

1. Site conditions pose acceptable risks, and no further action is warranted;
2. Site conditions pose a potential unacceptable risk that requires additional evaluation with a Tier 2 BERA; or
3. Site conditions pose a potential unacceptable risk, and accelerated site remediation is warranted.

As with the overall goals and objectives of the Tier 1 SRA, these decision criteria are consistent with the requirements of the NCP (Section 300.420). The Tier 1 decision criteria are addressed in Section 2.6.

2.1.3 Elements of the Tier 1 SRA

The Tier 1 SRA consists of two steps: an exposure evaluation and a risk characterization (Figure 2.1). The exposure evaluation identifies whether complete pathways exist that links potential site-associated contaminants with ecological receptors. In the case of incomplete pathways, some factor prevents contact of ecological receptors with contaminated media (i.e., soil contaminants are under a paved parking lot or building footprint). The screening assessment continues **only** for those contaminants for which a complete exposure pathway is indicated. In the risk characterization step, conservative assumptions are used to estimate exposure. Potential risks are estimated by the hazard

quotient approach, which compares the exposure estimates to screening values. The assessment will be based almost exclusively on data that are already available for the site. Conducting the SRA and the associated data needs are discussed in detail in the following sections of this guidance.

2.2 Planning Considerations

2.2.1 Overseeing the Tier 1 SRA

The goal of the RPM is to keep the site moving forward through the IR process, and doing so within the approved budget and schedule. As part of this process, the RPM is responsible for maintaining control and involvement over the risk assessment team and the risk assessment process. To effectively meet this responsibility, the RPM should work closely with the risk assessment team to make sure that you understand the rationale and uncertainties associated with all the aspects of the Tier 1 evaluation. This understanding should include, but not be limited to:

- Exposure scenarios,
- Data limitations, and
- Screening values.

One way to develop such an understanding is to hold regular coordination and status meetings with the project team. During these meetings, the RPM should not hesitate to ask questions about exposure assumptions, data evaluation methods, sampling plans, etc. Furthermore, the RPM should **not** proceed with any proposed activities until they have attained a clear understanding of all aspects of the proposed activities. Remember, if there is an inadequate understanding a particular activity, assumption, or evaluation, then it will be very difficult to adequately discus these issues with and address comments from the regulators and/or the public.

2.2.2 Team Identification

A large or diverse technical staff should not be required to conduct the Tier 1 SRA. Activities associated with Tier 1 are limited to compiling existing data, identifying complete pathways, developing a preliminary conceptual site model (CSM), and conducting screening-level risk estimation/characterization. These activities can typically be conducted by a single risk assessor coordinating with the technical staff responsible for the nature and extent characterization evaluations.

2.2.3 Regulator/Interested Party Involvement

After the Tier 1 SRA is completed, a report documenting the methods used and the results of the assessment will be prepared and distributed for regulatory approval.

Because the Tier 1 SRA is based on certain exposure assumptions and screening values, there is always the chance that the regulators may not agree with some of the assumptions or methods employed in the assessment, and therefore will reject the conclusions of the report.

To minimize the potential of such an occurrence, it is strongly recommended that the RPM initiate early regulator involvement in the SRA, with the goal of securing regulator concurrence and approval of the assumptions, data, exposure models, and screening values as early in the Tier 1 process as possible.

It may also be appropriate to involve other interested parties early in the process. By including such parties as the public and environmental groups early, you will be able to keep them informed about the progress of the SRA and help them understand how the risks are determined and how the consequent risk management decisions are made, thereby increasing the likelihood of their acceptance of the ultimate Tier 1 results and risk management decisions.

2.3 Exposure Pathway Evaluation

The exposure pathway evaluation addresses the following question: Are pathways present that link site contaminants to ecological receptors?

Pathway evaluation involves a number of data collection and evaluation activities:

- Conducting a site visit;
- Collecting existing site-specific chemical, physical, and biological data;
- Developing ecotoxicity profiles for the suspected contaminants;
- Identifying assessment endpoints, potential ecological receptors, and potential exposure routes; and
- Developing a preliminary CSM.

At the conclusion of the pathway evaluation, some contaminants that were initially included in the Tier 1process will likely be dropped from further consideration in the SRA because no complete pathways exist.

2.3.1 Site Visit

It is important that you, as the RPM, and your risk assessment team visit the site to be evaluated in the Tier 1 SRA. Such a visit provides you with a “real world” view of the site, and gives you insight into its ecological resources and its potential problems. The site visit is especially important in:

- Identifying areas or media that are contaminated (e.g., areas of “red water”, indicative of TNT residues);
- Identifying areas that show signs of adverse impacts (e.g., large areas of little or no live vegetation);

- Identifying the current land use;
- Identifying ecological resources (such as biota and habitats) present at the site that may be in contact with contaminated areas; and
- Formulating exposure pathways and identifying resources potentially at risk.

2.3.2 Data Requirements and Information Needs

Chemical Data

The principal data evaluated by the SRA are those that document environmental concentrations of site-related chemical constituents. These data may include those previously collected as part of the PA/SI for the site and those collected for other reasons such as a monitoring program.

Physical and Biological Information

Site-specific information should also be collected for the following other topics:

- The general site setting (e.g., industrial, residential, recreational).
- Physical features of the site (e.g., topography, surface and subsurface hydrology).
- The occurrence and distribution of habitats (e.g., wetlands, upland grassland, bottomland forest).
- The nature of the ecological resources (e.g., urban biota, waterfowl, birds of prey, large mammals).

Information on these topics will aid in identifying potential fate and transport routes, exposure mechanisms, and potential ecological receptors.

Process and Disposal Operations Knowledge

In addition to obtaining all available analytical data, an effort should be made to obtain historical and/or anecdotal information on process and disposal operations known or suspected to have taken place at the site. For example, discussions with "old-timers" may provide insight on past standard operating procedures related to waste disposal (e.g., "…waste solvents were burned-off in pits excavated in the northeastern portion of the site.") This information may help identify potential contaminants and areas of concern not immediately obvious from the site visit or suggested by the existing analytical data.

Collection of Additional Tier 1 Data

While the Tier 1 SRA should be based on existing data, there may be cases were some additional chemical data collection might be necessary in order to conduct the Tier 1 SRA evaluation. Collection activities **should not** include biological data (such as tissue samples, media for toxicity testing, or biotic surveys). Circumstances under which Tier 1 SRA chemical data collection may be appropriate include:

- Insufficient sample size. In some cases the available data may be very limited with respect to the total area of the site under investigation, or with regards to the media sampled. For example, your site may be 25 acres in size and include marine and

terrestrial environments. The available data might, however, be limited to five surface soil samples and groundwater data from a single monitoring well. In this case, the nature and number of samples are likely insufficient to adequately support a Tier 1 SRA.

- Inappropriate detection limits. For many contaminants, ecological receptors are more sensitive than human receptors. Because human health has historically taken precedence over ecological concerns, analytical method detection limits were typically set at levels appropriate for evaluating risks to human health but not for ecological evaluations. Thus, while there may be a large analytical data set for the site, the associated detection limits make these data unsuitable for use in the Tier 1 SRA.

- Incomplete analyte evaluation. In some cases, historical/anecdotal information on past activities and chemical use at the site may identify the potential for one or more chemicals to be present at the site, but for which analytical data are not available. In this case, it may appropriate to collect a limited amount of additional data to either confirm or refute a chemical as a potential contaminant for the site.

2.3.3 Identification of Preliminary Contaminants of Potential Ecological Concern

The evaluation of available data enables you to generate a list of chemicals that have been detected, or may be expected to occur, at the site under evaluation. These chemicals represent the preliminary Contaminants of Potential Concern (COPC) that will be further evaluated in the Tier 1 SRA.

The development of this list of COPCs should consider all media at your site and will result in the generation of a table identifying, by media, chemicals known or suspected to occur at your site. Additional information should include the range of reported concentrations together with the detection frequency, by media, for each COPC.

2.3.4 Development of Ecotoxicity Profiles

Information other than the reported media concentrations will be needed to effectively evaluate the COPCs for complete exposure pathways, and later to estimate risks. This information, presented as an ecotoxicity profile, includes:

- Toxic mechanism or mode of action for each COPC;
- Environmental fate and transport of each COPC; and
- Environmental and/or dose concentrations reported to cause adverse effects.

Information on the toxic mechanism (or mode) of action provides insight as to how (and which) ecological receptors could be exposed to and affected by a COPC. Environmental fate and transport information will identify where (and how) COPCs could be moving from the original release area (e.g., a landfill, an outfall, a spill area) to other media and

habitats. This information will play an important role in helping to identify the appropriate endpoints to be evaluated in the ERA. For example, if a contaminant were known to affect gill function in exposed aquatic biota, but does not affect fish-eating birds or mammals, then it would be inappropriate to select endpoints related to fish reproduction or targeting birds and mammals. Similarly, information regarding environmental fate and transport will help identify which media should be considered by the ERA, and this in turn affects selection of the assessment endpoints and receptor species.

This information on environmental fate and transport and toxicology will be used to develop screening values for the risk estimation (see Section 2.5.2 Screening Ecotoxicity Values). This information may be obtained from a variety of published sources, including certain regulations and statutes, the scientific literature, and published databases. The *Methods and Tools* portion of this web site identifies a variety of sources for such information.

2.3.5 Identification of Assessment Endpoints and Associated Ecological Receptors

Assessment Endpoints

The assessment endpoints represent those aspects of the ecosystem about which we are concerned. The EPA Superfund ERA guidance defines an assessment endpoint as "an explicit expression of the environmental value that is to be protected" from potential adverse effects of exposure to site contaminants.

The evaluation of potential risks to Tier 1 SRA assessment endpoints is based on the identification of potential adverse effects on ecological receptors, which include plant and animal populations and communities, habitats, or sensitive environments that may be exposed to site contaminants. Adverse effects should be related to such conditions as impaired reproduction, growth, or survival; changes in community characteristics; or decreases in habitat function.

Because Tier 1 represents a very conservative screening level assessment, the assessment endpoints will be stated in generic terms, such as "protection of a community from ecological changes related to contaminant exposure." This level of detail differs markedly from the identification of assessment endpoints in the Tier 2 BERA (see Section 3.3.1 of the Tier 2 portion of this website). Some examples of general assessment endpoints are:

- Maintenance of terrestrial bird populations at levels similar to those of nearby populations not exposed to site contaminants.
- Protection of aquatic communities from changes in structure or function resulting from exposure to site contaminants.
- Maintenance of fish populations at levels similar to those of nearby populations not exposed to site contaminants.

Additional information regarding assessment endpoints can be found in Section 3.3.1 and also in the *Issue Papers* portion of this web site.

Ecological Receptors as Surrogates for the Assessment Endpoints

Because of the very broad and generic nature of the Tier 1 assessment endpoints, it is not practicable to evaluate all components and aspects of those endpoints at this step of the SRA. Rather, the risk assessor should develop a manageable subset of receptors to serve as surrogates for the assessment endpoints. Appropriate receptors should include those that:

- Reflect important ecosystem components at your site;
- Are representative of the major trophic levels at your site; and
- Can serve as surrogates for 'important' species.

In this context, "important" means species valued by regulators or stakeholders for reasons other than that species' ecological importance. For example, state regulators may be specifically concerned about a recreational fishery, which by itself may or may not represent an important ecosystem component. In this case, it would be very advantageous to identify a receptor that could serve as a surrogate for both the "recreationally important" fish species and for ecologically important species. An endangered species represent another "important" species that may or may not represent an important ecosystem component. The bald eagle is a species that until recently was federally listed, and because of its listing was considered as "important." However, its ecological importance in any one area could be debated. In contrast, raptors (birds of prey) represent an important component of many ecosystems, representing the top trophic level and playing a major role in controlling small mammal populations. By selecting a raptor as a receptor to be evaluated in the SRA, you would be selecting a species that is representative of an important ecosystem component, that is representative of a major trophic level, and that could serve as a surrogate for an "important" species.

To identify ecological receptors for your site, begin with the identification of trophic levels or guilds associated with the different habitats. Then select surrogate species as representative of the broader trophic levels and guilds. Table 2.1 presents examples of the progression from habitat to trophic level to identification of ecological receptors. In this example, two primary habitats have been identified for the site under evaluation: a grassland habitat and a lake habitat. Four trophic levels are indicated for each habitat, and one or more ecological receptors considered representative of each habitat and trophic level are identified. In cases were screening values are provided or identified by the regulators (e.g., EPA soil screening values currently under development), particular species may be required for use as surrogates for broader trophic levels or guilds. Additional information regarding the development of screening values may be found in Section 2.5.2 of this portion of the guidance web site.

Regulator Concurrence

Because there could be differing views as to the environmental values that should be protected at your site, the assessment endpoints selected for evaluation by your risk assessor should be presented to the regulators for their review and concurrence. You should identify not only the endpoints themselves, but also the rationale supporting their selection as endpoints. Because the identification of receptors typically involves professional judgment, and will depend on the assessment endpoints identified for the site, you should seek to secure regulator concurrence before conducting the risk characterization for the ecological receptors selected for your site.

2.3.6 Identify Potential Exposure Pathways

The identification of potential exposure pathways will be based on an evaluation of the environmental fate and transport of contaminants from one environmental medium to another, together with the identification of possible exposure routes from environmental media to biota.

Environmental fate and transport mechanisms to be considered include:

- Surface runoff,
- Groundwater transport and discharge,
- Sediment transport,
- Volatilization, and
- Airborne particulate emission.

Each represents a mechanism by which a contaminant may be released from one location and medium and be transported to another location, potentially contaminating additional media.

Exposure routes represent the mechanisms by which the ecological receptors may be exposed to the contaminants and include contaminant transport directly from the media to the biota and also from biota to biota via food uptake. These exposure routes include:

- Ingestion of contaminated food,
- Ingestion of contaminated media,
- Inhalation of contaminated media, and
- Direct contaminant contact and uptake across body surfaces.

Different fate and transport mechanisms will be important for different COPCs. Similarly, different exposure routes will be important for different ecological receptors.

2.3.7 Develop a Preliminary Conceptual Site Model and Identify Complete Exposure Pathways

The Preliminary Conceptual Site Model

The conceptual site model (CSM) is defined as "a written description and visual representation of the known, expected, and/or predicted relationships between the site COPCs and the ecological receptors." The CSM depicts the risk assessment team's current knowledge of the site under evaluation. The model identifies:

- Contaminant sources,
- Fate and transport mechanisms,
- Exposure routes, and
- Assessment endpoints and ecological receptors.

In the Tier 1 SRA, the CSM is designated as preliminary because it identifies generic assessment endpoints. In contrast, the CSM developed to support the Tier 2 BERA is more detailed and includes identification of measurement endpoints. Figure 2.2 provides an example of a Tier 1 preliminary CSM.

Such a graphical depiction of what is known about your site aids in the identification of complete exposure pathways by providing an easy-to-use template against which each individual COPC identified for your site may be compared and evaluated. The CSM also serves as a very useful communication tool when discussing your site with the regulators or the public. A PC-based software package for constructing CSMs can be found on the *Methods and Tools* portion of this website.

Identification of Complete Exposure Pathways

The identification of complete exposure pathways involves an evaluation of the preliminary CSM to identify those COPCs for which the fate and transport mechanisms and exposure routes indicate a likelihood of contaminants moving from a source (an environmental medium) to one or more receptors.

To conduct this evaluation, each COPC is applied to the preliminary CSM and followed to an ecological receptor. For an exposure pathway to be considered complete, the evaluation must identify both:

- A known or likely transport mechanism for moving the COPC to a location (or medium) where an ecological receptor may be exposed; and
- An exposure route by which the COPC can be taken up by the receptor.

Keep in mind that because multiple exposure pathways are possible for any one COPC and because pathway completeness will differ among different ecological receptors, the pathway evaluation should address all possible COPC-receptor pairs.

2.3.8 Outcome of the Exposure Pathway Evaluation

At the conclusion of the exposure pathway evaluation, your risk assessor will identify those COPCs for which complete pathways are known or expected. These are the COPCs that should be carried on to the next step of the Tier 1 SRA (Figure 2.1). Those COPCs for which no complete pathway has been identified should be deleted from further evaluation within Tier 1. It is critical that the basis for the elimination of COPCs on the basis of incomplete exposure must be clearly supported and presented in the SRA report that documents the results of the Tier 1 SRA and the resultant risk management decision.

It is highly unlikely that no complete pathways will be identified for any of the COPCs under evaluation. However, the most likely outcome of exposure pathway evaluation will be the complete elimination of some COPCs from further evaluation and the partial elimination (with regards to a specific environmental medium or a particular habitat) from further evaluation of other COPCs.

2.4 Exposure Estimation

Once COPCs with complete pathways have been identified, the Tier 1 SRA can move to the next step of the Tier 1 SRA evaluation: exposure estimation and risk calculation (Figure 2.1). Exposure represents the contact between a COPC and an ecological receptor and includes considerations of magnitude, frequency, and duration of exposure.

Because of the conservative nature of the Tier 1 SRA, the magnitude, frequency, and duration of exposure should be considered to be at their maximum, as should the bioavailability of each COPC. All the receptors are considered to be exposed to the maximum reported concentration of a COPC 100% of the time; and at their most sensitive life stage (e.g., egg, larvae, juvenile, adult).

In addition, exposure estimates for some receptors will use maximum ingestion rates and minimum body weights, and a COPC bioavailability of 100%. For biota that feed on more than one food type, the diet will be considered to consist of whichever type of food is most contaminated, 100% of the contaminant dose is assimilated into the receptor tissues and is available for transfer to the next trophic level (assimilation efficiency).

Exposure estimation is simplest for biota dwelling in surface water and sediment (such as invertebrates and fish) and for terrestrial vegetation. For these receptors, exposure is considered to occur via direct contact (absorption through body surfaces and/or ingestion) with a contaminated medium and is considered to occur at the maximum reported COPC concentration.

For higher organisms such as birds and mammals, the primary exposure route is typically considered to be ingestion of contaminated food or environmental media, and exposure is estimated as a contaminant dose. For these receptors, uptake models taking the following general form are used to predict the dose:

Dose = C x IR x F x SUF x AE x BA

where:

Dose = the daily dose of the COPC received by the receptor,

C = the concentration of the COPC in the food or the ingested medium,

IR = the ingestion rate of food or medium by the receptor,

F = the fraction of the food or medium in the total diet of the receptor,

SUF = site use factor, calculated as the receptor home range divided by the site area,

AE = assimilation efficiency, and

BA = bioavailability of the COPC.

For the Tier 1 SRA, default values should be:

C = the maximum reported concentration,

IR = the highest available rate reported in the literature or estimated allometrically,

F = 1.0 (100% of the diet is contaminated),

SUF = 1.0 (receptors spends 100% of its time on the site),

AE = 1.0 (100%), and

BA = 1.0 (100%).

These input parameters are termed exposure factors, and are the same parameters that are used in the dose models employed in Step 3a of the Tier 2 BERA, but with less conservative (i.e., AE, BA, and SUF each less than 100%) and more site-specific values replacing the Tier 1 SRA conservative values. Additional details regarding dose modeling are presented in the *Methods and Tools* portion of this web site and also in the EPA Wildlife Exposure Factor Handbook (EPA 1993a). This handbook also inlcudes exposure factor values for a variety of common wildlife species. Click here to view or download the Exposure Factor Handbook chapter that addresses dose modeling.

To derive an exposure estimate, the preliminary CSM should be used to identify all potential complete pathways to the receptor. Once these pathways are identified,

individual dose models (of the general form identified above) should be developed for each pathway. A dose is calculated for each COPC exposure pathway, and a total dose is estimated by summing the doses for all appropriate pathways. For example, a mouse may be exposed by ingesting contaminated food, contaminated soil, and contaminated water. To estimate the total COPC dose to the mouse, the risk assessor calculates a dose for each of these exposure pathways and then sums the three doses to obtain a total dose. This process is then repeated for each COPC-receptor pair under evaluation.

At the conclusion of the exposure estimation, the risk assessor will have generated a list of COPCs together with dose estimates for each ecological receptor and each pathway under evaluation. These exposure estimates will then be used to estimate ecological risks.

2.5 Risk Estimation

At this point in the Tier 1 SRA process, the risk assessor has gathered all the available data for your site, developed a listing of COPCs to be evaluated, identified several assessment endpoints and ecological receptors for the site, developed a preliminary CSM of the site, identified complete exposure pathways linking the site contamination to the endpoints and receptors, and estimated exposures to the receptors as either media concentrations or doses. This information will now be used to estimate the potential risks that the site COPCs may pose to the assessment endpoints (as represented by the ecological receptors) identified for the site. These risk estimates will then be used by the RPM to make a risk management decision regarding the site being evaluated.

2.5.1 Hazard Quotient Approach

For the Tier 1 SRA, risks are estimated using the hazard quotient (HQ) method, which is a simple approach commonly used in human health risk assessment to evaluate risks from noncarcinogens. The HQ method compares the exposure estimates to literature-derived effects concentrations to provide a quantitative risk estimate, the HQ.

The Hazard Quotient (HQ)

The HQ is simply the ratio of the exposure estimate to an effects concentration considered to represent a "safe" environmental concentration or dose. Following EPA Superfund Guidance terminology, this "safe" effects concentration is termed a screening ecotoxicity value (SEV). Derivation of SEVs is presented in the next section of this guidance.

The HQ is calculated with the following equation:

$$HQ = (\text{Exposure Estimate}) \div SEV$$

where:

HQ = the hazard quotient.

Exposure Estimate = either the maximum environmental concentration or the calculated dose estimate, and

SEV = screening ecotoxicity value.

Values of the HQ may range from less than 0.1 to ∞, with values less than 1.0 considered indicative of acceptable risk. In the Tier 1 SRA, the risk assessor will calculate an HQ risk estimate and generate a list of HQ values for each COPC-receptor pair. Table 2.2 presents an example of HQ estimates for two receptors and multiple contaminants. For each COPC-receptor pair, HQs should be calculated for the total exposure estimate and for each complete pathway. Calculation of HQ values for individual pathways may permit identification of the pathways and media potentially posing the greatest degree of unacceptable risk to the receptor. This information may then be used to focus the Tier 2 BERA if one is initiated. For the previous mouse dose example, HQ values would be calculated for the food ingestion pathway, the water ingestion pathway, and the soil ingestion pathway, as well as for the total dose from all three of these pathways.

The HQ approach has a number of features that make it particularly useful for estimating risks. First, it is a relatively simple and quick, and thus inexpensive, calculation. Secondly, because risk acceptability is based on comparison of the calculated HQ value to a single critical value (HQs < 1.0 indicate acceptable risks, while HQs $\geq$ 1.0 indicate unacceptable risks) it is very easy to communicate the results not only to the regulatory community but also to the public. Third, the HQ approach provides an efficient method for identifying low risks and very high risks for which risk management decisions may not require additional information. For example, an HQ of 10,000 may be considered to pose an immediate and very unacceptable risk that may warrant immediate action, while an HQ < 0.1 may immediately support a no further action (NFA) management decision. Lastly, the HQ approach is the approach used in human health risk assessments (HHRA) for evaluating risks from noncarcinogenic contaminants. Thus, its use in the Tier 1 SRA is comparable to the approach that will be used at your site for the HHRA.

The Hazard Index (HI)

For each receptor, some risk assessors (especially in human health evaluations) sum the HQs for all contaminants to provide a single risk estimate for all the contaminants. That parameter is termed a hazard index (HI). Because of the large degree of uncertainty regarding the cumulative effects of multiple contaminants, NAVFAC does **not** recommend the use of HIs unless adequate rationale is provided to support the summation of the individual HQ values. If the regulators request HIs, the RPM should request supporting rationale from the regulator regarding the validity of summing HQ values. Furthermore, if an HI is to be calculated, HQs should be summed **only** for COPCs that have similar toxic modes of action. This information would have been

previously identified during the development of the ecotoxicity profiles (see Section 2.3.4).

2.5.2 Screening Ecotoxicity Values

What Are SEVs?

Calculation of the HQ requires comparison of the exposure estimate to a "safe" effects concentration, the SEV. The SEV is a contaminant-specific (and often species-specific) media or dose concentration considered to be "safe" to ecological receptors. These values are preferably based on concentrations at which chronic exposure has been reported to cause no observed adverse effects; these concentrations are referred to as NOAELs (no-observed-adverse-effects levels). These values are typically determined in laboratory studies involving standardized laboratory animals. The Navy should not develop SEVs from experimental studies. Rather, SEVs will be developed for contaminant-specific information that is available in the scientific literature and/or provided by the regulators.

How Are SEVs Developed?

While there is currently no promulgated approach for developing SEVs, most risk assessors use an approach that derives the SEVs from chronic NOAEL values. If a chronic value is unavailable for a particular chemical, the development of the SEV will be based on other effects values, such as chronic lowest-observed-adverse-effects-level (LOAEL), or subchronic or acute NOAELs or LOAELs. Risk assessors often apply modifying factors when using values other than chronic NOAELs to develop SEVs. For example, only a chronic LOAEL may be available for the contaminant of interest. In such a case, the risk assessor may divide the chronic LOAEL by a modifying factor such as 10 or 100 and use the resultant value as the SEV. Such an approach is considered to provide a very conservative value. This approach is commonly used to develop screening values for HHRAs. The modifying factors can go by a variety of names; most commonly they are referred to as uncertainty factors. Current EPA Superfund ERA guidance calls them adjustment factors and identifies a value of 10 to be used for developing NOAEL values from LOAEL values.

The availability of NOAEL data is the most limiting factor affecting the development of SEVs. In addition, effects data are typically available for laboratory organisms rather than for naturally occurring wildlife species. As a consequence, few of the SEVs that the risk assessor identifies will be specific for species that are likely to occur at your site. To minimize uncertainties associated with the use of non-species-specific data, the risk assessor should use effects data from biota as taxonomically similar as possible to the ecological receptors selected for evaluation in the assessment. Because physiology (and thus likely contaminant effects) differs more and more as species become more and more taxonomically different, NOAEL values should not be extrapolated across taxonomic classes or orders. For example, suppose the deer mouse has been selected as an ecological receptor for your site. The use of NOAEL values developed for a white laboratory mouse may be used as the NOAEL for the deer mouse. In contrast, NOAEL

data for the Japanese quail, which is commonly used in avian toxicity tests, should not be used for the deer mouse.

Sources of Data

Few nationally accepted values are currently available for conducting screening level ERAs. Exceptions are the EPA (1986) Ambient Water Quality Criteria (AWQC), which identify chronic and acute water concentrations considered to be protective of freshwater and marine aquatic biota. These values may be used directly as SEVs for calculating HQs for aquatic biota.

A number of national and regional lists of SEVs have been developed by a variety of agencies, including EPA, NOAA, and FWS. Site-specific screening values that have been developed for the Oak Ridge National Laboratory (ORNL) have been used by a variety of agencies at sites across the country. In addition to these sources of SEVs, a great variety of toxicity data exist from which SEVs may be developed. Some of these sources include EPA databases, FWS publications, and the open scientific literature. A listing of national, state, and international sources of benchmark values is provided in the *Methods and Tools* portion of this web site, and additional information on soil screening benchmarks is provided in an issue paper in the *Issue Papers* portion of this web site.

Most available SEVs are for surface water and sediment. Few SEVs are currently available for soil. One source of soil SEVs is the screening values developed by ORNL for terrestrial vegetation and soil-dwelling invertebrates. A national working group (chaired by EPA and including DoD, DOE, and the private sector) that is developing a set of national soil SEVs is expected to release some values in the near future. The Navy is a member of that working group, and you should contact EFA North with any questions regarding availability of the national soil SEVs and soil-screening values in general.

Regulatory Concurrence

The SEVs used in the Tier 1 SRA should be agreed upon by all parties (the Navy and the regulators) before you conduct the risk estimation and present your risk management decision. By involving the regulators early, you minimize the likelihood of their not agreeing with the risk assessment results and your risk management decision for the site. It may also be appropriate to include other interested parties such as Trustees in these early interactions.

Not all SEVs or SEV-development methods will be equally acceptable to all regulators. For example, EPA Region 4 has issued a set of values to be used when conducting a screening ERA at military installations within the region, and these will be the values expected by the Region 4 regulators. For some sites, the regulators have asked that the screening ERA be conducted with SEVs from a variety of sources.

The SEVs selected for use at your site, their sources, and the methodology used to develop them, should be presented to the appropriate regulators as early in the Tier 1 SRA as possible. Final selection and regulator concurrence with the values, methods, and

data sources will be determined through discussions among the risk assessors, the RPM, and the appropriate regulators. This selection represents a negotiation point in the Tier 1 SRA and should be documented. For sites were the regulators have predetermined the values to be used (such as in EPA Region 4), minimal discussions and early concurrence will be necessary. For sites where the regulators have not developed a required SEV list, the RPM, working with the risk assessor, should develop an SEV list (and the appropriate supporting rationale) and propose those values to the regulators. Again, document all discussions and subsequent agreements regarding the SEVs.

2.5.3 Outcome of the Risk Estimation

Identification of Contaminants of Potential Concern

At this point in the Tier 1 process, the risk assessor has collected all available data, identified assessment endpoints and ecological receptors, developed a preliminary CSM, and identified all complete exposure pathways, completed the exposure estimation, and calculated HQs to estimate risks. The risk assessor will then identify those COPCs with HQs > 1.0; these become the COPCs that will be evaluated for the Tier 1 SRA risk management decision and in the Tier 2 BERA, if one is initiated. Those COPCs with HQs <1.0 are eliminated from further consideration in the Tier 1 SRA. By going through the Tier 1 SRA process, the risk assessor has taken what was likely a large list of COPCs and reduced it to a smaller list by using a set of defensible criteria that have been agreed upon by the regulators. Thus, should the site require further evaluation in the form of a Tier 2 BERA, the scope, effort, and costs of the Tier 2 evaluation will be focused on those contaminants most likely to pose an unacceptable risk, rather than the much larger set of contaminants present at the site.

Contaminant Elimination and Data Adequacy

Before final identification of COPCs for elimination from further consideration, the risk assessor should re-evaluate the available data to determine whether they are adequate to sufficiently characterize the extent and nature of the contamination. For example, even though the SRA determined an HQ < 1.0 for a particular COPC, the risk assessment team should consider whether the available data from five sample locations are sufficient to adequately characterize a 25-acre site. The analytical data should also be evaluated with regards to historical process knowledge. If process knowledge suggests the release of a particular chemical, but this chemical is not included in any of the available analytical data, data adequacy may be an issue. If you decide that there are insufficient samples, then elimination of the COPC on the basis of an HQ < 1.0 would be inappropriate. In this case, some additional media sampling may be warranted. Data adequacy and additional sampling needs should be considered early in the Tier 1 process. These issues, as well the collection of additional Tier 1 data, are discussed in more detail in Section 2.3.2.

2.6 Decision Criteria and Risk Management

2.6.1 Decision Criteria for Exiting the Tier 1 SRA

Following completion of the risk estimation and the identification of the COPCs (those COPCs with HQs $\geq$ 1.0), the RPM must now make a risk management decision regarding future site activities. There are two decision criteria for exiting the Tier 1 SRA process (Figure 2.1):

1. The site passes the SRA on the basis of an absence of complete exposure pathways and/or an absence of unacceptable risks (all HQs < 1.0). Under these conditions, the decision is made that the site poses acceptable risks to ecological resources, further ERA or site remediation is unwarranted, and the site may be closed out for ecological concerns.

2. The site fails the SRA on the basis that complete pathways and unacceptable risks (HQ $\geq$ 1.0) are indicated for at least one contaminant. Under these conditions, the decision is made to either initiate interim cleanup or proceed to Tier 2.

It is highly unlikely that a site will successfully pass the initial screen. Rather, most sites will fall under the second decision criterion. In this case, only the COPCs (those contaminants with HQs $\geq$ 1.0) will be considered for accelerated cleanup or further evaluation under Tier 2.

2.6.2 Interim Cleanup vs. Tier 2

If the site fails the screen, then the risk management decision will focus on whether to implement an interim cleanup or to proceed to a Tier 2 BERA. The RPM, together with input from the risk assessor, should consider a number of issues when making this decision:

1. **What are the implications of selecting interim cleanup vs. proceeding to a Tier 2 BERA?** Consider issues such as cost, policy, and social concerns. For example, in some cases it may be more cost effective to implement interim cleanup than to conduct a Tier 2 BERA, especially if the site is small and the volume of contaminated media is small. Alternately, the results of the Tier 2 assessment may indicate that remediation is not warranted, thus incurring a significant cost savings. As another example, there may be considerable public pressure to do something at your site. In this case, if the SRA identifies unacceptable risks and the site is small, it may be not only cost effective to implement an interim cleanup, but such a decision could go a long way in placating the public's desire to see some level of cleanup.

2. **If interim cleanup is selected, what might be the implications of the Tier 1 Preliminary Cleanup Goals on the scope and cost of the cleanup?** If interim

cleanup is selected, preliminary remediation goals (PRGs) must be developed. PRGs represent the target contaminant media concentration levels for the cleanup. These PRGs are derived by back-calculating the media or dose concentrations so that the HQs = 1.0 or less. For media-based HQs, the PRG will be the SEV, even though the EPA Superfund ERA guidance specifically states that SEVs are not defensible cleanup goals, and should not be used as such. For dose-based HQs, the PRG will be a function of the SEV and the very conservative dose models, and the resultant back-calculated PRG will be very low. Use of these low PRGs may result in cleanup volumes that are likely much greater than necessary, resulting in higher than necessary costs.

3. **How might the ecological impacts of interim cleanup compare with the impacts of not taking action?** Interim cleanup may require the elimination of certain habitats and result in the loss of some ecological resources. Given the nature of the resources affected and of the interim action, restoration of the impacted habitats may be very difficult. Implementing an interim action may cause more harm than good, especially if there is a high degree of uncertainty associated with the SRA.

4. **How might the risk characterization change following the Tier 2 re-evalutaion of the SRA assumption?** The first step of the Tier 2 BERA, Step 3a, involves the re-evaluation of the Tier 1 results through the use of more realistic (less conservative) exposure assumptions. For example, Step 3a may utilize a SUF of 0.5 rather than 1.0, and AE and BA assumptions of less than 100%. Use of such less conservative values in the dose models will result in lower dose estimates and subsequently lower HQ risk estimates. Depending on the extent of the modeling revisions, HQs < 1.0 may now be indicated for one or more of the COPCs previously retained by the SRA. These can now be eliminated from further consideration, and no remediation for the site may be warranted. Proceeding with interim cleanup precludes the conduct of Step 3a, and may thus result in a cleanup that may not have been necessary. Step 3A is discussed in detail in Section 3 of the *Ecorisk Process* portion of this web site.

In general, interim cleanup may be considered when:

- The SRA identifies unacceptable risks indicated by very high (>100) HQs,
- The site is small and the contaminant boundaries are well-defined,
- The cost for cleanup is relatively small, and
- Implementation impacts are expected to be minor.

Interim cleanup should not be considered when:

- There insufficient information regarding the nature of the contamination and the subsequent risks,

- The site is large and not well delineated,

- Implementation impacts may be severe, and

- The SRA identifies unacceptable risks, but these do not greatly exceed an HQ of 1.0.

2.7 Documentation

Documentation of the Tier 1 SRA should include two components: (1) documentation of all discussions, negotiations, and subsequent concurrence among the Navy and the regulators; and (2) an SRA report.

Documentation should be maintained regarding all meetings and discussions related to issues such as:

- Data adequacy;
- SEVs, their sources, and justification for development;
- Assessment endpoints and ecological receptors;
- Dose models and modeling assumptions; and
- Other negotiated issues or topics that may arise.

Negotiated items related to the SRA goals, assessment endpoints, data sources, and other issues may be documented in a Technical Approach Memorandum.

After the Tier 1 process is complete, an SRA report must be prepared and submitted to the regulators for review, comment, and concurrence. This report should include the following information:

- A description of the site and the known or suspected releases;
- The chemical data used in the assessment, including information on analytical methods and detection limits;
- The assessment endpoints and ecological receptors, including the rationale for their selection;
- The preliminary CSM;
- All exposure models and exposure scenarios used in the assessment, together with all supporting rationale and sources of supporting information;
- The SEVs, together with their sources and/or methods used for their development;
- All modeling results;
- All risk estimation (HQ values) and risk characterization results; and
- The risk management decision, including supporting rationale.

Because this report will serve as the primary vehicle for communicating the results of the SRA and your risk management decision to the regulators and the public, it is critical that

this report not only be technically correct, but that it also be well written (clear, concise, and thorough). The Navy has established an Ecological Risk Assessment Technical Assistance Team (ERTAT) to provide technical support, including document review, to Navy sites conducting ecological risk assessments. Click here for information on how to obtain assistance from this group.

2.8 Questions and Issues to Discuss with Your Risk Assessor

Throughout the Tier 1 SRA, you must strive to understand the SRA process as fully as possible. It will be your job later to make and potentially defend a risk management decision for your site, a decision that is supported in part by the results of the SRA. If you do not adequately understand the basis and rationale for the various assumptions, evaluations, and decisions made during the SRA, you run the risk of making an inappropriate decision, having an appropriate decision challenged by the regulators or public because of difficulties you had in communicating the SRA, or being forced to redo part or all of the assessment because certain data, assumptions, and evaluations were not appropriate. Because you have worked with your risk assessment team throughout the Tier 1 process, you should have a very good understanding of how the SRA risk estimates were derived and what they potentially mean for your site. The following items represent questions and issues that you should discuss with your risk assessment team throughout the SRA, and continue to discuss until you feel comfortable with your level of knowledge regarding that issue.

1. Are the characterization data adequate (with regards to sample size and spatial or temporal coverage) for conducting an SRA?

2. How were the assessment endpoints and ecological receptors selected?

3. Is the process excluding any ecological receptors that may be considered as "important" by the regulators or the public? If so, what might be involved to include these receptors in the SRA?

4. Why were some potential exposure pathways identified as incomplete?

5. Were the SEVs provided as part of the regulators guidance, or did we derive these ourselves? If the latter, what data and approach were used in their derivation?

6. What assumptions were used in uptake models?

7. If HIs were calculated, what HQs were summed and what was the rationale for summing the individual HQs?

8. What do the estimated risks mean ecologically? Is there a potential for serious disruption of ecosystem structure or function? What might be the magnitude and extent of potential impacts – large or small?

9. What part of the SRA might the regulators or public most disagree with? Why? What could we do to minimize this concern?

10. If we select interim action, what might be the ecological impacts associated with such a decision? What may we need to do to restore the impacted resources? How quickly might we expect the impacted areas to recover?

Figure 2.1 The Tier 1 Screening Risk Assessment Process

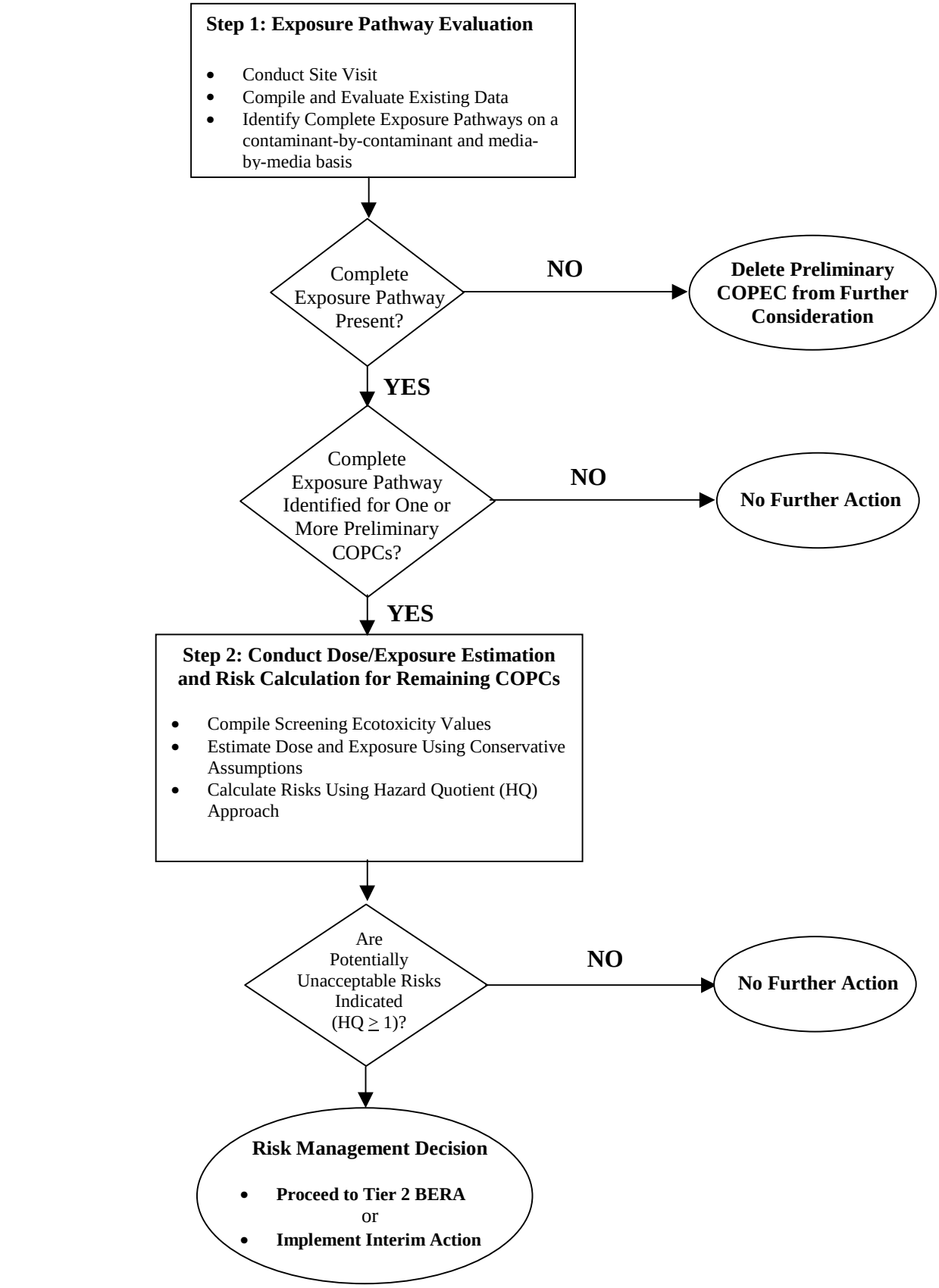

Figure 2.2 Example of a Preliminary Conceptual Site Model

[Note that the model identifies assessment endpoints (e.g., primary producers, primary consumers), contaminant sources and media (landfill, soil, sediment, surface water), environmental transport mechanisms (surface runoff, groundwater transport), and exposure routes (direct uptake, ingestion). (SAV = submerged aquatic vegetation)]

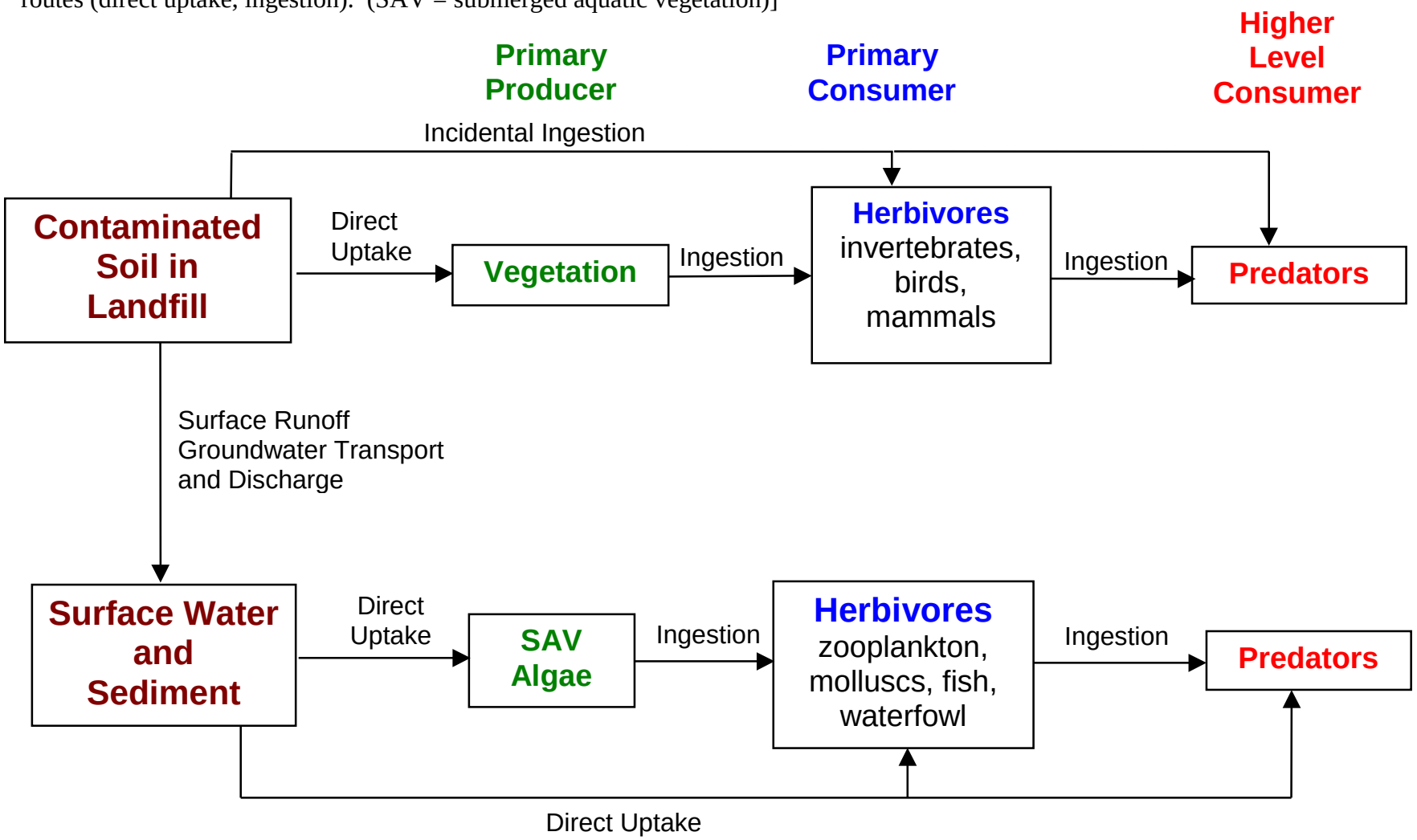

Table 2.1 Possible Progression from Habitat to Receptor during the Identification of Tier 1 Ecological Receptors

In this example, two primary habitats have been identified for the site under evaluation: a grassland habitat and a lake habitat. Four trophic levels are indicated for each habitat, and one or more ecological receptors considered representative of each habitat and trophic level are identified. The final composition of the receptor list will be a function of the specific assessment endpoints identified for the site, as well as discussions and concurrence among the Navy and the regulators.

Habitat	Trophic Level	Ecological Receptors
Grassland	Primary Producer (Plants)	Grasses
	Primary Consumer (Herbivore)	Harvest Mouse
	Secondary Consumer (Omnivore)	Red Fox
	Tertiary Consumer (Predator)	Red-Tailed Hawk
Lake	Primary Producer (Plants)	Algae
		Submerged Aquatic Vegetation
	Primary Consumer (Herbivore)	Zooplankton
		Benthic Invertebrates
		Fish
	Secondary Consumer (Omnivores)	Fish
		Great Blue Heron
	Tertiary Consumer (Predator)	Osprey
		Kingfisher
		Great Blue Heron

Table 2.2 An example of dose-based Hazard Quotient (HQ) estimates for the deer mouse and the red-tailed hawk

In this example, the values in the dose column represent the sum of the individual pathway doses estimated for the receptor, and the HQ estimates is for the total dose estimate. Note that only the HQ calculated for the cadmium-deer mouse pair exceeds a value of 1.0 and thus indicates a potentially unacceptable risk. SEV = screening ecotoxicity value.

Receptor	Contaminant	Dose (mg/kg-d)	SEV (mg/kg-d)	HQ
Deer Mouse	Aluminum	0.001	2.1	<0.1
	Cadmium	**21.3**	**1.9**	***11.2***
	Chromium	0.001	6.6	<0.1
	Iron	4,200	NA	NA
	Lead	5.7	16	0.3
	Zinc	15.4	320	<0.1
	PCB (total)	0.0001	0.18	<0.1
Red-tailed Hawk	Aluminum	0.001	110	<0.1
	Cadmium	0.23	1.45	0.2
	Chromium	0.001	1.00	<0.1
	Iron	0.58	NA	NA
	Lead	0.58	3.85	0.2
	Zinc	1.5	14.5	0.1
	PCB (total)	0.001	0.18	<0.1